ALLERGY RELIEF 25 MG- diphenhydramine hcl 25mg capsule Ulai Health LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient (in each banded capsule)

Diphenhydramine HCl 25 mg

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat
- temporarily relieves these symptoms due to the common cold:
- runny nose
- sneezing

Warnings

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- take every 4 to 6 hours, or as directed by a doctor
- do not exceed 6 doses in 24 hours

adults and children 12 years and over	1 to 2 capsules
children 6 to under 12 years	1 capsule
children under 6 years	ask a doctor

Other information

• store at 20-25°C (68-77°F)

Inactive ingredients

black iron oxide, D&C red #28, FD&C blue #1, FD&C red #40, gelatin, lactose monohydrate, magnesium stearate, silicon dioxide, sodium lauryl sulfate

Questions or comments?

(866) 562-2756 (Mon- Fri 8 AM to 4 PM EST)

PHARBEST

NDC 73057-348-08

Manufactured in the USA

*COMPARE TO the active ingredient in

BENADRYL®ALLERGY ULTRATAB®

ALLERGY RELIEF

Antihis tamine - Diphenhydramine HCl 25 mg

- Itchy, Watery Eyes Runny Nose
- Itchy Throat Sneezing

100 CAPSULES



■ take every 4 to 6 hours, or as directed by a doctor ■ do not exceed 6 doses in 24 hours (866) 562-2756 (Mon-Fri 8 AM to 4 PM may increase drowsiness **=** use caution 1 to 2 capsules operating machinery - excitability may occur, especially in children Keep out of reach of children. In case alcohol, sedatives, and tranquilizers If pregnant or breast-feeding, ask a health professional before use. contact a Poison Control Center right away (1-800-222-1222). children under 6 years ask a doctor silicon dioxide, sodium lauryl sulfate 8 STOP PEELING monohydrate, magnesium stearate Inactive ingredients black iron oxide, D&C red #28, FD&C blue #1 1 capsule of overdose, get medical help or when driving a motor vehicle or FD&C red #40, gelatin, lactose Questions or comments? store at 20-25°C (68-77°F) **Drug Facts** (continued) children 6 to under 12 Other information adults and children 12 years and over Directions Vears

ALLERGY RELIEF 25 MG

diphenhydramine hcl 25mg capsule

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73057-348
Route of Administration	ORAL		

Active Ingredient/Active Moiety Ingredient Name Basis of Strength DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6 JAD40) (DIPHENHYDRAMINE - DIPHENHYDRAMINE HYDRO CHLO RIDE 25 mg

Inactive Ingredients			
Ingredient Name	Strength		
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)			
D&C RED NO. 28 (UNII: 767IP0 Y5NH)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GELATIN (UNII: 2G86QN327L)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			

MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics			
Color	pink (Pink/ Clear)	Score	no score
Shape	capsule	Size	14mm
Flavor		Imprint Code	PH0 14
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73057-348- 08	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2019	
2	NDC:73057-348- 03	24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2019	
3	NDC:73057-348- 11	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 7/0 1/20 19	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2019	

Labeler - Ulai Health LLC (081181535)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(73057-348), analysis(73057-348), pack(73057-348), label(73057-348)

Revised: 7/2019 Ulai Health LLC